

IN THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application:

Listing of Claims:

1-6. (Canceled)

7. (Previously Presented) An integrated device comprising:

(a) a case;

(b) a pad;

(i) disposed within the case and,

(ii) capable of receiving and transporting a biological sample containing an analyte;

(c) a detector:

(i) in fluid communication with the pad (b);

(ii) disposed within the case (a); and

(iii) adapted for at least one of detecting the presence and quantitating the concentration of analyte in the sample;

(iv) said detector being capable of being in contact with a display for illustrating results of the detector; and

(d) a strap or adhesive tape for holding the pad to an area of skin surface, wherein:

(e) the case (a) includes at least one opening suitable to allow the biological sample containing analyte to contact the pad (b).

8. (Previously Presented) The integrated device of claim 7 wherein the pad (b) contains a surfactant to facilitate transport of the biological sample containing analyte across the pad (b).

9-31. (Cancelled)

32. (Currently Amended) The integrated fluid harvesting and analysis device of claim 64, and further comprising a sealed electrical connection to at least one of the sensor (c) and a probe via the ~~final~~ first means.

33-50. (Cancelled)

51. (Previously Presented) A method for harvesting interstitial fluid from tissue and analyzing the interstitial fluid, said method comprising the steps of:

(a) porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;

(b) collecting the sample from the opening,

wherein:

(c) step (b) is enhanced by applying a vacuum to the selected area of the skin;

(d) the sample is collected in an article comprising:

(i) a pad capable of receiving the sample and

(ii) a strap or adhesive tape for holding the pad to the selected area of skin,

(e) the article contains an opening suitable to allow the sample to contact the pad; and

(f) determining the amount of analyte within the sample.

52-54. (Cancelled)

55. (Previously Presented) An apparatus for obtaining biological fluid for diagnostic testing, said apparatus comprising:

(a) a device for forming an opening in an area of skin suitable for extracting a sample comprising interstitial fluid;

(b) a vacuum device for introducing a vacuum onto the area of skin so as to enhance interstitial fluid flow from the skin;

(c) wherein the vacuum device is capable of controlling the pressure level and/or timing of the vacuum.

56. (Previously Presented) The apparatus according to claim 55 wherein the vacuum device is capable of maintaining the vacuum at a desired pressure level.

57. (Previously Presented) An apparatus for obtaining biological fluid for diagnostic testing, said apparatus comprising:

(a) a first device for forming an opening in an area of skin suitable for extracting a sample of biological fluid;

(b) a second device for introducing a positive pressure to the area of skin to assist in the fluid flow from the opening,


wherein:

(c) the second device is capable of controlling the timing and/or the amount of pressure on the area of skin.

58. (Currently Amended) The apparatus according to claim 57:

[[(a)]] further comprising (d) a vacuum device for introducing a vacuum onto the area of skin so as to enhance fluid flow from the opening;

[[(b)]] wherein:

 (e) the second device is capable of controlling the pressure level and/or timing of the vacuum.

59. (Previously Presented) The apparatus of claim 57 wherein the sample comprises blood.


60. (Previously Presented) The apparatus of claim 57 wherein the sample comprises interstitial fluid.

61 and 62. (Canceled)

63. (Previously Presented) An integrated fluid harvesting and analysis device,
comprising:

- (a) a first layer;
- (b) a porating element:
 - (i) disposed on the first layer (a);
 - (ii) adapted for forming at least one opening in tissue;
- (c) a sensor:
 - (i) positioned in fluid communication with the at least one opening in the tissue;
 - (ii) responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid; and
- (d) a mechanical element:
 - (i) having a small opening therein;
 - (ii) capable of receiving the first layer (a) and the sensor (c) such that the porating element (b) is aligned with the small opening; and
 - (iii) responsive to downward force thereon to cause the surface of the tissue to bulge into the small opening.

64. (Previously Presented) An integrated fluid harvesting and analysis device,
comprising:

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- (a) a first layer;
 - (b) a porating element:
 - (i) for forming at least one opening in tissue;
 - (ii) disposed on the first layer (a);
 - (c) a sensor:

(i) positioned in fluid communication with the at least one opening in the tissue;

(ii) responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid;

(d) first means for pneumatically sealing the first layer (a) and the sensor (c) to the surface of the tissue and forming a sealed chamber; and

(e) second means coupled to the first means d) for supplying negative pressure to the sealed chamber.

B1